



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,376	05/30/2001	Jeffrey P. Bodner	279.368US1	7232

21186 7590 10/18/2006

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. BOX 2938  
MINNEAPOLIS, MN 55402

EXAMINER
----------

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
----------	--------------

3766

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/870,376

Applicant(s)

BODNER

Examiner

Frances P. Oropeza

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 8/4/06 (RCE) & 7/10/06 (Amendment).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-13,15-18,20,23-26 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-13,15-18,20,23-26 and 28-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Request for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 8/4/06 has been entered.

2. In the response filed 7/10/06 the Applicant amended the independent claims, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

***Claim Rejections - 35 USC § 103***

3. Claims 1-7, 9-13, 15-18, 20, 22, 24-26, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cobain et al. (US 5796044) in view of Helland et al. (US 5545201).

Cobain et al. teach a lead assembly with two co-axial and non co-radial single filar or multi-filar conductors. The second conductor is disposed within the first conductor, and the first and second conductors may have an insulative coating disposed directly thereon surrounding the outer filar surface such that a cross-section of the outer filar surface is surrounded by the insulative coating, the coating being a polyurethane (abstract; col. 2 @ 36-40; col. 4 @ 7-23; col. 5 @ 12-60; col. 7 @ 58-67; col. 9 @ 66 –col. 10 @ 14). All leads have flexibility; the disclosed lead has flexibility enabling placement in the heart (col. 8 @ 1-6).

Art Unit: 3766

As to claims 3, 4, 6, 13 and 17, an insulative sleeve (38)/ tube/ sheath/ redundant insulation is disposed between the first and second conductor, the sleeve made of polyethylene (fig. 9; col. 4 @ 11-15; col. 11 @ 4-6). The internal sheath (27) is optional (col. 8 @ 44-47).

As to claims 5, 10, 11, 15, 16, 18 and 22, the sleeve/ sheath/ coating can be made of a non-silicon polymer such as polyurethane, ETFE, PTFE, and PFA (col. 5 @ 57-67; col. 11 @ 4-6; col. 12 @ 42-50).

As to claims 9, 13, 17 and 20, the first conductor is insulated (22) (fig. 9; col. 11 @ 4-9).

As to claims 11 and 18, an extendable/ retractable electrode is taught (col. 8 @ 1-14).

As to claim 30, when the insulative sleeve (38) is formed by coating or extrusion, the sleeve forms a tight intimate bond with the second conductor, hence the tubular insulative sleeve rotates relative to the first conductor (col. 4 @ 7-15; col. 5 @ 12-60; col. 11 @ 4-6).

As discussed in the previous five paragraphs of this action, Cobain et al. disclose the claimed invention except for a means for facilitating rotation of the second conductor relative to the first conductor (1, 11 and 30)

Helland et al. teach an electrode configuration using an electrode assembly with an extendable/ retractable electrode (144) coupled to the second conductor, the electrode rotated by the means for facilitating rotation/ conductive plug (176) for the purpose of fixing/ securing the electrode to the heart wall. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an extendable/ retractable electrode coupled to the second conductor, the electrode rotated by the means for facilitating rotation/ conductive plug in the Cobain et al. system in order to accurately sense and stimulate the heart so there is accurate discrimination of the cardiac rhythm enabling effective therapy to be offered to the patient (figure 6; col. 1 @ 6-11 and 48-58; col. 1 @ 62 – col. 2 @ 5; col. 4 @ 56 – col. 5 @ 15).

Art Unit: 3766

4. Claims 23-26, 28 and 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cobain et al. (US 5796044) and Helland et al. (US 5545201) in view of Nelson et al. (US 6249708).

As to claim 26, Cobain et al. teach the sleeve/ coating can be made of a non-silicon polymer such as polyurethane, ETFE, PTFE, and PFA (col. 5 @ 57-67; col. 12 @ 42-50).

As to claims 28 and 29, Cobain et al. teach the first conductor is insulated (22) (fig. 9; col. 11 @ 4-9).

As to claim 25, Cobain et al. teach an extendable/ retractable electrode (col. 8 @ 1-14).

As discussed in paragraph 2 and the previous three paragraphs of this action, modified Cobain et al. teach applying various Teflon™ materials such as PTFE and ETFE on the second outer coil diameter and over the insulation (col. 5 @ 57-67; col. 12 @ 42-50), but do not teach applying heat shrunk Teflon™ material on the second outer coil diameter and insulation (claims 23 and 24).

Nelson et al. teach lead construction using heat-shrunk Teflon™ (38) for the purpose of insulating the central core conductor (34). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a heat-shrunk Teflon™ PTFE or ETFE to on the second outer coil diameter and insulation in the modified Cobain et al. system in order to reinforce the assembly and provide a proven alternate approach of applying Teflon™ to the second outer coil diameter and insulation, hence adding flexibility in the lead manufacturing process (col. 4 @ 27-45; col. 7 @ 46-48).

5. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cobain et al. (US 5796044) and Helland et al (US 5545201) in view of Altman et al.

Art Unit: 3766

(US 5845396). As discussed in paragraph 2 of this action, modified Cobain et al. disclose the claimed invention except for the first outer filar and the second outer filar being coated with polyimide.

Altman et al. teach lead construction using polyimide as a coating for cables/filars for the purpose of insulating the conductors. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a polyimide coating in the modified Cobain et al. system in order to utilize the proven alternate coating material of polyimide to insulate the conductors, hence adding flexibility in the lead manufacturing process by defining an alternate material of construction (col. 2 @ 34-37).

#### *Statutory Basis*


6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3766

*FPO*  
10/10/06

  
Robert E. Pezzuto  
Supervisory Patent Examiner  
Art Unit 3766